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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,094	02/09/2005	Boris P. Kovatchev	3053,128.US	4378
26474 7590 04/06/2010 NOVAK DRUCE DELUCA + QUIGG LLP 1300 EYE STREET NW SUITE 1000 WEST TOWER WASHINGTON, DC 20005				
EXAMINER CLOW, LORI A				
ART UNIT		PAPER NUMBER		
1631				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,094

Applicant(s)

KOVATCHEV ET AL.

Examiner

LORI A. CLOW

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2010.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-226 is/are pending in the application.
4a) Of the above claim(s) 40-111 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-39 and 112-226 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

In view of the Appeal Brief filed on 13 January 2010, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner has approved of reopening prosecution by signing at the conclusion of this Office Action.

Claims 1-226 are currently pending. Claims 40-111 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 28 November 2007. Claims 1-39 and 112-226 are examined herein.

Claim Rejections - 35 USC § 101-Non-statutory Subject Matter

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-18, 112, 113, 135-154, and 195-214 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. It is noted that in the previous Office Action the Examiner mistakenly left out claims 112 and 113. However, since these are also drawn to methods, these claims also stand rejected herein.

Claims 1-18, 112, 113, 135-154, and 195-214 are drawn to a methods for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data comprising the steps of pre-processing data, estimating HbA_{1c}, validating the estimate, and transforming the estimate to a visual depiction for output.

In accord with the decision in *In re Bilski* (cited below), a claim to a process or method must meet the machine-or-transformation test in order to be eligible under 35 USC 101 as statutory subject matter (*In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008)). In other words, the prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept may have a practical application, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (*Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673, 1972), as clarified in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008) the test for a method claim is whether the claimed method is (1) tied to a particular machine or apparatus or (2) transforms a particular article to a different state or thing.

In the instant case, the method claims are not so tied to another statutory class of invention because the method steps that are critical to the invention are "not tied to any **particular apparatus or machine**" and they do not provides a transformation to a different state or thing and therefore do not meet the machine-or-transformation test as set forth in *In re Bilski* 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008).

Response to Applicant's Arguments as presented in the Appeal Brief filed 13 January 2010

1. Applicant argues that there is "nothing abstract about glycosylated hemoglobin, blood glucose levels, or a patient from which glucose data is collected". Applicant further states that "all are physical phenomena" and therefore, "the claims are directed to a specific evaluation of the composition of a diabetic patient's blood for assessment of a potential hypoglycemic condition, and communicating the evaluation to a user, so that a proper medical treatment may be administered to a patient".

While the Examiner appreciates the application of the instant invention, the claims do not recite a physical step, such as for instance, "collection of a blood sample for evaluation" nor do the claims recite a transformation of data to a different state or thing. It is maintained that "electronically transforming an estimate into a visual depiction" is not central to the purpose of the claimed subject matter. The instant claim estimates are not generated by a specific machine and therefore do not represent a claimed process that "is limited to a practical application of a fundamental principal to transform *specific data*" (*In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (P. 26, Federal Circuit, 2008)). The data herein can be computed by any general purpose computer and therefore cannot be statutory.

It is again noted that the instant rejection could be overcome, for example, by performing a critical method step on a suitably programmed computer or processor or by providing a physical step such as mentioned above.

2. Applicant argues that “the appealed claims to a specific method of estimating the glycosylated hemoglobin of a patient and communicating the estimate to a user, are directed to a method that pertains to the analysis of quantitative physical characteristics of a physical patient, and that has a practical application in the prevention or treatment of an adverse physical condition of the patient. Because the claimed method is applied to data representative of the physical element of a patient’s blood composition, it meets the ‘transformation’ test because it converts SMBG data representative of blood glucose, to an estimate of HbA_{1c} data representative of glycosylated hemoglobin”.

While the above facts are appreciated and acknowledged, the argument is not persuasive. The Examiner is not asserting that the claims do not provide a practical application. Rather, under the new Guidelines for examination of nonstatutory subject matter (see Interim Examination Instructions at <http://www.uspto.gov/web/patents/policyprocedures.htm>) the claims are evaluated for meeting the two prong machine-or-transformation test. In the instant case, as detailed above, the claims do not meet the analysis. The claims do not, as Applicant seems to indicate, meet the transformation test by merely taking *data representative* of the physical element of a patient's blood and converting it to another type of data (SMBG data) because no transformation has taken place. If the claims recited a step of “collecting a blood sample from a patient” and then went on to “process the blood to calculate BG data” and then to further use that data in the remainder of the claimed method steps, then the claim would meet the

"transformation" arm of the test. However, as the claims recite instantly, this is not the case and the rejections are maintained.

Claim Rejections - 35 USC § 112-2nd paragraph

The outstanding claim rejections under 35 USC 112, 2nd paragraph have been withdrawn in view of Applicant's arguments.

The rejections set forth below constitute a new grounds of rejection based on further consideration of the instant claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 8-10, 24, 26-28, 120, 122-124, 140, 142-144, 160, 162-164, 180, 182-184, 200, 202-204, 220, and 226 and those claims dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of the recited claims above and those claims dependent therefrom recite, "using a predetermined mathematical formula defined as". The claims are vague and indefinite because each of the recited claims fails to recite any such mathematical formula. Rather, the claims merely define certain criteria, such as "scale" and "risk" etc...without any association to an actual formula and therefore it is unclear as to what is being computed. Clarification through the recitation of an *actual* formula is requested.

It is noted that claims 11, 29, 39, 112, 114, 125, 145, 165, 185, and 205 and the claims dependent therefrom actually recite a mathematical formula defined by HbA_{1c} being = to the

EST2 and HbA_{1c} being = to $0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RH11 + 1.873325$ wherein the estimating is defined by the formula.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 5, 19, 23, 37, 38, 135, 139, 155, 159, 175, 179, 195, 199, 215, 219, 221, and 225 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovatchev et al. Diabetes Care (1997) Vol. 20, No. 11, pages 1655-1658; PTO Form 1449 reference). This is a new grounds of rejection.

The instant claims are drawn to methods for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data comprising the steps of pre-processing data, estimating HbA_{1c} , validating the estimate, and transforming the estimate to a visual depiction for output.

Kovatchev et al teach a system and method for symmetrization of blood glucose measurement by a logarithmic data transformation that matches the clinical and numerical center of the blood glucose scale to make the data symmetric (abstract). The logarithmic

transformation makes the transformed blood glucose scale symmetric around zero, thus defining a clinical and numerical center point, which makes 6.25 mmol/l the center of the blood glucose scale and the transformed blood glucose readings distribution normal and serves as the basis for defining blood glucose risk indexes which given multiple SMBG readings, predict the subjects glycosylated hemoglobin levels and the likelihood of severe hypoglycemia (page 1655, column 2). Kovatchev et al. teach conversions of mg/dl and mmol/l at page 1656, columns 1 and 2. Based on the transformations, a low and high blood glucose index was also developed (page 1656, column 2). Thus, Kovatchev et al. teach each of the instant claim limitations.

2. Claims 1, 19, 37, 38, 135, 155, 175, 195, 215, and 221 are rejected under 35 U.S.C. 102(e) as being anticipated by 6,421,633 (Heinonen et al.; July 16, 2002 with priority to May 21, 1998). This is a new grounds of rejection.

The instant claims are drawn to methods for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data comprising the steps of pre-processing data, estimating HbA_{1c} , validating the estimate, and transforming the estimate to a visual depiction for output.

Heinonen et al. teach a method and system whereby levels of HbA_{1c} are predicted using a mathematical model which is derived to predict the behavior of HbA_{1c} relative to blood glucose (abstract; column 2, lines 20-53), therefore meeting the limitations of converting BG data and estimating HbA_{1c} and providing an output of the data (Figure 6).

No Claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

April 6, 2010
/Lori A. Clow, Ph.D./
Primary Patent Examiner
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/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631

